



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,969	04/21/2000	Donald G. Wallace	17067-002040	6560
44444	7590	11/12/2004	EXAMINER	
BAXTER HEALTHCARE CORPORATION ONE BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/553,969	Applicant(s) WALLACE ET AL.	
	Examiner Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6-14-2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 19-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 19-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

Receipt of amendment and remarks dated 6-14-2004 is acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-14-2004 has been entered.

Claims 1 and 19-36 are pending.

The following new rejection is applied to the pending claims:

Claim Rejections - 35 USC § 102

Claims 1, 20-23, 25, 30 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,818,517 to Kwee et al (Kwee).

Kwee et al discloses a pharmaceutical preparation comprising a hydrogel polymer and a drug, which is introduced by means of an injection syringe, which reads on the instant applicator having an extrusion orifice. Kwee teaches that the composition provides water necessary for the preparation of the highly viscous hydrogel that is already part of the total composition (col. 1). Thus, the composition of Kwee does not contain any free aqueous phase other than the water that forms a part of the hydrogel. Kwee teaches that the polymer has a swelling capacity but does not state the claimed percentages. However, Kwee teaches dextrin as a suitable polymer (examples), which is a polysaccharide and thus the swelling capacity is inherent to dextrin of Kwee et al.

Art Unit: 1615

Further, the claimed property of in vivo degradation time being less than one year is inherent to the polymer because Kwee teaches the same class of polymer i.e., a polysaccharide.

Claim Rejections - 35 USC § 103

Claims 19, 24, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee).

Instant claims are directed to protein and non-biological hydrogel and particle size of the hydrogel. While Kwee does not explicitly teach the claimed features, Kwee teaches a hydrogel polymer and suggests polymers such as dextran, starch, polyvinyl alcohol, etc (col. 2) are capable of swelling in water and homogenously injected out of the syringe without causing any practical problems and release the drug slowly over a period of time. Further, Kwee teaches that the polymer is in the form of dry particles (claims) and also suggests that the hydrogel can be used in combination with any drug such as locally active drugs, bactericidal, anti-inflammatories, etc. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use a particulate natural or synthetic (non-biological) polymer such as polyvinyl alcohol, having an appropriate particle size, as a hydrogel in combination with the any desired drug because Kwee suggests that the dry particulate polymer which has a capability to swell is useful in releasing the drug over a long period of time without having the conventional drawbacks such as water being separated from the hydrogel during injection at the site of interest.

Claims 26-29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee) in view of Berg et al.

Art Unit: 1615

Kwee fails to teach the claimed protein polymer, a clotting agent such as thrombin, or the claimed combination of polymers.

Berg teaches a collagen wound dressing material comprising resorbable collagen particles of 50 to 350 microns. Berg also teaches addition of several wound-healing agents such as growth factors, enzyme inhibitors, angiogenesis factors etc (col. 4). Berg teaches that collagen wound dressings are capable of swelling at the desired ratios and still be injectable (examples 5 and 10). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ particulate collagen of Berg as a hydrogel in the teachings of Kwee and use the hydrogel alone or in combination with the hydrogels of Kwee for releasing drugs such as wound healing agents because Berg suggests that collagen dressings are capable of being resorbable, allow cellular in growth, and protect the wound to be treated while still permitting the required diffusion of gases and liquids.

Response to Arguments

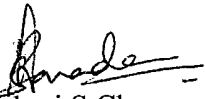
Applicant's arguments with respect to claims 1 and 19-36 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
November 9, 2004